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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/084,471	05/22/1998	PATRICIA D. MURPHY	5371.31.US02	5585

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 01/16/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/084,471

Applicant(s)

MURPHY et al.

Examiner

S. Zitomer

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 22, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 61-86 is/are pending in the application.
- 4a) Of the above, claim(s) 61 b)-d) and 62-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61, 85, and 86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## DETAILED ACTION

### Application status

1. Receipt of applicant's response and corrected Sequence Listing filed October 22, 2001, paper no. 21, is acknowledged.

### Election without traverse

2. Applicant's election without traverse of species A., BRCA2 nucleotide sequence comprising exon 15 sequence with T at position corresponding to nucleotide 171 of SEQ ID NO:2 (claim 61(a)), in Paper No.21 is acknowledged. As stated in the previous Office action mailed August 21, 2001, paper no. 20, only claims drawn to the elected nucleic acid/nucleotide position species and claims drawn to a nucleic acid encoding the amino acid residue corresponding to the elected nucleotide species would be examined. As applicant has not identified any claim in the latter category, only the former has been examined. Accordingly, claim 61 b)-d) and claims 62-84 have been withdrawn from prosecution as being drawn to independent and distinct inventions under 35 U.S.C. 121. See paragraphs 3 and 4 of paper no. 20. Dependent claims 85 and 86 have also been examined with limitation of 85 a) to "a nucleic acid molecule as forth in [claim 61 a)]".

### Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention

3. Claims 61 a), 85 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because "the" nucleotide sequence of "the" BRCA2 gene of which the claimed nucleic acid molecule is comprised is not identified. The specification mentions two BRCA2 gene sequences, those of GenBank and BIC, at page 2, which are stated to be inaccurate, and six other BRCA2 sequences designated by the superscript "omi" at page 6. Therefore, it is unclear whether "the" BRCA2 sequence is any one of these, a particular one or some other sequence in the art or in the specification and one of skill in the art would not be apprised of the scope of the claimed invention. The nucleotide sequence, SEQ ID NO:2, was searched against prior art

sequences by Science and Technology Information Center technicians. However, as SEQ ID NO:2 does not represent the claimed "nucleotide sequence of the BRCA2 gene" a full search was not possible.

**Conclusion**

4. **No claim is allowed.**

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*S. Zitomer*

Stephanie Zitomer, Ph.D.

January 12, 2002